

REMARKS

Reconsideration and allowance of the present application is respectfully requested in view of the foregoing amendments and the following additional remarks which have addressed all the issues raised in the December 02, 2005, Office Action or otherwise have rendered them moot.

Claims 1-3, 7 and 9 are now under consideration in this application.

Claims 1-3, 7 and 9 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Ferreira et al., as evidenced by Gajhede et al. (Clinical and Experimental Allergy, 1999, Vol. 29, pages 478-487).

Claims 3 and 7 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for not further limiting the base claim.

The claim amendments are in order to more particularly define and distinctly claim applicants' invention and/or to better recite or describe the features of the present invention as claimed. No new matter is believed to be added. Support for the amendment to claim 1 can be found on page 5, fourth paragraph of the specification as filed.

Withdrawal of Premature Final Rejection

Applicants respectfully ask the Examiner to reconsider and withdraw the finality of the rejection. According to MPEP 706.07(a), second or any subsequent actions on the merit shall not be final where the Examiner introduces a new ground of rejection that is neither necessitated by applicant's amendments of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c).

The Examiner cites Ferreira et al. allegedly because it discloses peptides that are derived from Bet v 1, wherein said peptides have a single mutation and are 15-19 amino acids in length and in pharmaceutical compositions. As discussed in detail below, Ferreira et al. is directed to at least a six-point mutant of Bet v 1. Further, Applicants find no support in Ferreira for the alleged 15-19 amino-acid length asserted by the

Examiner. Accordingly, it is submitted that Applicants' amendments did not necessitate the rejection in view of Ferreira, thus making this final rejection premature. Applicants respectfully ask that it be withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 3 and 7 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to further limit claim 1. Applicants traverse as follows.

Claim 7 is now canceled making this ground for rejection moot as to claim 7.

Regarding claim 3, the Examiner is asked to respectfully consider the "at least three preferably consecutive amino acids" language of claim 1 as setting a lower limit in terms of the solvent exposed amino acids. Claim 3 is therefore a proper dependent claim by further limiting the lower limit to five consecutive amino acids. Accordingly, there is no basis for this ground for rejection as applied to claim 3 and Applicants ask that it be withdrawn as well.

Rejections under 35 U.S.C. § 102(b)

Claims 1-3, 7 and 9 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Ferreira et al., as evidenced by Gajhede et al. (Clinical and Experimental Allergy, 1999, Vol. 29, pages 478-487). The Examiner asserts that Ferreira et al. discloses peptides derived from Bet v1, wherein said peptides have a single mutation and are 15 – 19 amino acids in length and in pharmaceutical compositions (pages 232 – 233). The Examiner further asserts that Gajhede et al., discloses the solvent exposed residues in Bet v1, and at least peptide 1-18 as disclosed in Ferreira et al., thus meeting the limitation of three consecutive solvent exposed amino acids. Applicants respectfully disagree and traverse as follows.

Ferreira et al. teaches the use of at least six-point mutants of Bet v 1

The Examiner's attention is drawn to page 234, column 2, last three lines of paragraph 1, wherein Ferreira et al. declared: "All isoallergen mutants presented here and their corresponding amino acid substitutions are schematically shown in Figure 1."

Directing the Examiner's attention to Figure 1 on page 235, Ferreira et al. teaches the use of a six-point mutant of Bet v1, identified as Bet v1 a, having point mutations in positions 10, 30, 57, 112, 113 and 125. Similarly, the mutant Bet v1 a (A1) is a six-point mutant which differs from Bet v1a itself by a single point mutation in position number 30. The same goes for other point mutants of Bet v1 a disclosed in Figure 1. However, these point mutants of Bet v1 a are themselves six-point mutants of Bet v1. As such the Examiner's assertion that Ferreira teaches single point mutants of Bet v1 is in error. The same analysis goes for the seven-point mutant Bet v1d of Ferreira et al.

Applicants' contention that Ferreira et al. teaches at least six-point mutants of Bet v1 is also amply supported elsewhere in the Ferreira et al. publication. In the Abstract on page 231, the publication teaches: "We found that IgE binding to Bet v1 depended on at **least six amino acid** residues/positions. Immunoglobulin analyses and inhibition experiments showed that the **multiple-point** Bet v1 mutant exhibited extremely low reactivity with serum IgE from birch pollen-allergic patients."

On page 232, column 1, paragraph 3, Ferreira et al. declared: "By using a method developed to predict functional residues in proteins, we obtained a list of most common residues likely to influence IgE binding to Bet v1... Based on the results of this analysis, we introduced point mutations at critical positions in the sequence of Bet v1 .." On page 232, column 2, paragraph 3, Ferreira et al. teaches: "To generate a Bet v1a construct carrying six-point mutations, the following approach was used."

The bottom line is that the Bet v1a and Bet v1d isoforms and point mutations thereto are at least six-point mutants of Bet v1, consistent with the teachings of Ferreira et al. and do not anticipate, nor make obvious the single point mutants of the present invention.

Ferreira et al. does not teach Bet v1 mutants having 15 – 19 amino acid residues

The Examiner asserts that Ferreira et al. teaches Bet v1 mutants having 15 – 19 amino acid residues. Applicants disagree. Nowhere did Ferreira et al. teach fragments of Bet v1, let alone those having only 15 – 19 amino acids. Instead Ferreira et al. teaches six-point **isoforms** of Bet v1 having mutations in six-positions deemed critical to IgE binding. See Ferreira et al. page 232, column 1, paragraph 3. Figure 1 on page 235

clearly shows Ferreira et al. Bet v1 mutants identical in length to Bet v1, but for point mutations in at least six-positions. Thus, not only does Ferreira et al. not teach fragments of Bet v1, it does not teach fragments having 15 – 19 amino acid residues.

Ferreira et al. does not teach Bet v1 mutants surface-exposed peptides for the focusing of IgG antibodies

Ferreira et al. describe Bet v.1 multi-point mutants with reduced IgE reactivity but maintained T cell epitopes. The peptides referred to by the Examiner were used by Ferreira et al. to demonstrate the presence of T-cell epitopes in the mutant proteins but otherwise have nothing in common with the surface exposed peptides that are described and claimed in the present invention.

In fact, the T cell epitope-containing peptides mentioned in Ferreira et al. result from proteolytic processing of antigens. They are presented by antigen-presenting cells by MHC to T cell receptor of T cells. Contrary thereto, the claimed peptides of the present invention relate to such peptides which induce IgG antibodies response in B cells and are recognized by surface antibodies of B cells but not T cells.

In view of the foregoing, there is no basis for maintaining a 35 U.S.C. § 102 rejection and Applicants respectfully ask that this ground for rejection be withdrawn.

CONCLUSION

All of the stated grounds for rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn and the claims allowed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

REED SMITH, LLP

Date: _____

By: _____

Toni-Junell Herbert

Reg. No. 34, 348

Date: 02/01/2006

By:  _____

Christopher E. Aniedobe

Reg. No. 48, 293

3110 Fairview Park Dr.
Suite 1400
Falls Church, VA 22042
(703) 641-4203

32256
PATENT TRADEMARK OFFICE